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# EXHIBIT 12

# Case: 1:17-md-02804-DAP Doc #: 3443-13 Filed: 08/31/20 2 of 5. PageID #: 499793



WATSON PHARMACEUTICALS, INC.
CORPORATE STANDARD OPERATING PROCEDURE
DOCUMENT #: CSOP 011-004 REVISION #: 02

TITLE: Suspicious Orders of Controlled Drugs

SECTION:

011 Sales and Marketing

PAGE:

1 of 4

EFFECTIVE DATE: 04/07/2009

## PURPOSE:

To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

## SCOPE:

**DEFIN** 

This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

#### DOCUMENT REFERENCES:

**Document Number** 

CTMAN 080-023-CC-OPR

Action

C	CTMAN 080-045	License Entry and Maintenance
NIT	ONS:	
•	DEA	Drug Enforcement Administration – A component of the Justice Department whose regulations enforce 21CFR, Part 1300 to end.
	SOMS	Suspicious Order Management System

**Document Title** 

Order Processing

## PROCEDURE:

Responsibility

	1.0	Process for Suspicious Orders of Controlled Drugs		
by eac accom		AP system compiles a past history of controlled substance drug product orders h customer to establish a normal order size and order frequency. This is plished through the normal Sales Order process (see CTMAN 080-023-CC-order Processing, for details on this process).		
Controlled Substance Compliance	1.2	The Controlled Substance Compliance Department determines the SOMS Multiplier Table.		
Management		1.2.1 See CTMAN 080-045, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information.		



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Responsibility	<u>Actio</u>	<u>n</u>
Master Data Administrator	1.3	If a processed order generates a SOMS excessive order flag in SAP (See CTMAN -80-023-CC- OPR, Order Processing), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Controlled Drug (SOMS)
	1.4	The Master Data administrator will review the SOMS report, and then, if warranted, contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order.
	1.5	Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the Master Data Administrator and submitted to the Manager for review, and signature.
	1.6	The Master Data Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The Master Data Administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the Master Data administrator will escalate the suspicious order to the next level.
Call Center Management	1.9	Determine if the order does or does not classify as suspicious.
Management	1.10	If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department.
Controlled Substance Compliance Department	1.11	The Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration.

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1.12 File a copy of the SOMS Report, along with the customer purchase order, in the

suspicious order record file.

Master Data

Administrator



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## **CHANGE HISTORY:**

Initiation / Change Control Number	Revision Number	Effective Date	Change Summary
C2004-0260	00	05/03/2004	New CSOP.
C2005-0317	01	09/19/2 <u>0</u> 05	"Agency" changed to "Administration".  "involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end".  1.3 Change Responsibility from "Order Processing Representative" to "License Administrator".  1.4 "if warranted" added to action.  1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration."  1.12 Change Responsibility from "Order Processing Representative" to "License Administrator".

## **CHANGE HISTORY (in HotDox):**

HotDox Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	See effective date in header.	Change all reference of Licensing Administrator Title to: Master Data Administrator  Change all reference of CTMAN 080-041-CC-OPR – to CTMAN 080-023-CC-OPR  1.2 The SOMS Multiplier Table is determined by the Controlled Substance Compliance Department. – Delete " Call Center Management"  1.3 "Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. – Change -Order Processing to Master Data Administrator – Delete" and email it to the License Administrator"  1.5 "the Supervisor or Management for review, and signature" Remove – Supervisor or.

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WATSON PHARMACEUTICALS, INC.

CORPORATE STANDARD OPERATING PROCEDURE

DOCUMENT #: CSOP 011-004 REVISION #: 02

TITLE: Suspicious Orders of Controlled Drugs

SECTION: 011 Sales and Marketing

PAGE: 4 of 4 EFFECTIVE DATE: 04/07/2009

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Date: Friday, 27 February 2009, 06:28 AM Pacific Time

Meaning: I have authored this document.

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Date: Friday, 27 February 2009, 07:29 PM Pacific Time Meaning: I have reviewed and approved this document.

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Date: Tuesday, 03 March 2009, 08:35 AM Pacific Time Meaning: I have reviewed and approved this document.

UserName: Tracey Hernandez (tlherna)
Title: Dir, Controlled Substance Compliance

Date: Monday, 16 March 2009, 08:10 AM Pacific Time Meaning: I have reviewed and approved this document.

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